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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,580	11/21/2003	Frederic Beseme	105045.01	3397
25944	7590	09/23/2005	EXAMINER	
OLIFF & BERRIDGE, PLC			MCGILLEM, LAURA L	
P.O. BOX 19928			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22320			1636	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,580

Applicant(s)

BESEME ET AL.

3

Examiner

Laura McGillem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.



Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:1, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:1, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:1. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:1, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
2. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:2, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:2, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:2. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:2, a complementary sequence and an

- equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
3. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:3, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:3, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:3. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:3, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
 4. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:4, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:4, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:4. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:4, a complementary sequence and an

- equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
5. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:5, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:5, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:5. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:5, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
 6. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:6, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:6, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:6. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:6, a complementary sequence and an

- equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
7. Claims 1-3, 5-10, 12-17, 20, 25-27 and 30-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:7, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:7, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:7. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:7, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
 8. Claims 1-3, 5-10, 12-17, 20, 25-27 and 30-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:8, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:8, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:8. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:8, a complementary sequence and an

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- equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
9. Claims 1-3, 5-10, 12-17, 20, 25-27 and 30-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:9, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:9, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:9. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:9, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
10. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:10, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:10, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:10. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:10, a complementary sequence and an

equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.

11. Claims 1-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:11, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:11, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:11. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:11, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
12. Claims 1-3, 5-10, 12-17, 20, 25-29 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:12, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:12, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:12. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:12, a complementary sequence and an

- equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
13. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:13, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:13, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:13. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:13, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
14. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:14, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:14, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:14. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:14, a complementary sequence and an

- equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
15. Claims 1-3, 5-10, 12-17, 20, 25-27 and 31-35, drawn to a nucleic material comprising a nucleotide sequence of SEQ ID No:15, a complementary sequence and sequences that exhibit at least 70% or 90% homology for every 100 contiguous monomers in the sequence of SEQ ID No:15, or a nucleotide sequence that encodes any polypeptide exhibiting, for every contiguous sequence of at least 30 amino acids, at least 80% or 90% identity with a peptide sequence encoded by a functional part of SEQ ID No:15. Further, this group is drawn to a nucleic acid fragment comprising a nucleotide sequence of at least 100 bases of a clone of SEQ ID NO:15, a complementary sequence and an equivalent sequence which has at least 50% homology to said sequence, nucleic probes, and a diagnostic composition, classified in class 536, subclass 23.1.
 16. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:16, classified in class 536, subclass 24.31.
 17. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:17, classified in class 536, subclass 24.31.
 18. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:18, classified in class 536, subclass 24.31.
 19. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:19, classified in class 536, subclass 24.31.

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20. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:20, classified in class 536, subclass 24.31.
21. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:21, classified in class 536, subclass 24.31.
22. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:22, classified in class 536, subclass 24.31.
23. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:23, classified in class 536, subclass 24.31.
24. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:24, classified in class 536, subclass 24.31.
25. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:25, classified in class 536, subclass 24.31.
26. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:26, classified in class 536, subclass 24.31.
27. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:27, classified in class 536, subclass 24.31.
28. Claim 11, drawn to a nucleic probe or nucleic primer comprising a nucleotide sequence of SEQ ID No:28, classified in class 536, subclass 24.31.
- 29-43. Claims 18-19, drawn to a method for the molecular labeling of at least one member selected from the group consisting of an autoimmune disease, a pathology associated with an autoimmune disease, a pathological pregnancy and an unsuccessful pregnancy comprising identifying and quantifying any nucleotide

fragment comprising one nucleotide sequence from the group of SEQ ID Nos:1-15, classified in class 435, subclass 6.

44-58. Claim 21, drawn to a method of diagnosing an autoimmune disease, a pathology associated with an autoimmune disease, a pathological pregnancy or an unsuccessful pregnancy comprising contacting a biological sample with a molecular marker comprising a nucleic material comprising one nucleotide sequence from the group of SEQ ID Nos:1-15, classified in class 435, subclass 6.

59-73. Claims 22-24, drawn to a method for diagnosing susceptibility to an autoimmune disease, a pathology associated with an autoimmune disease, a pathological pregnancy or an unsuccessful pregnancy, and detecting a gene associated with susceptibility to a pathology associated with an autoimmune disease, a pathological pregnancy or an unsuccessful pregnancy comprising contacting a biological sample with a proximity marker comprising a nucleic material comprising one nucleotide sequence from the group of SEQ ID Nos:1-15, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-28 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are patentably distinct because they each have

uniquely different nucleotide compositions which are not obvious over each other. The search required for one of the sequences would not be the same for any of the other sequences and therefore a search for all claimed sequences would be burdensome.

Inventions 1-15 and 29-43 are related as product and process of use. Inventions 1-15 are drawn to a group of patentably distinct nucleic acid sequences selected from the group of SEQ ID NOs:1-15, and Inventions 29-43 are drawn to a method of using a nucleotide fragment selected from the group of SEQ ID NOs:1-15. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a nucleotide sequence selected from the group of SEQ ID NOs:1-15 could be used in a materially different process for using that product such as for diagnosing an autoimmune disease, a pathology associated with an autoimmune disease, a pathological pregnancy or an unsuccessful pregnancy.

Inventions 1-15 and 44-58 are related as product and process of use. Inventions 1-15 are drawn to a group of patentably distinct nucleic acid sequences selected from the group of SEQ ID NOs:1-15, and Inventions 44-58 are drawn to a method of using a nucleotide fragment selected from the group of SEQ ID NOs:1-15. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

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using that product (MPEP § 806.05(h)). In the instant case, a nucleotide sequence selected from the group of SEQ ID NOs:1-15 can be used in a materially different process for using that product such as for diagnosing susceptibility of a disease or for detecting a gene associated with susceptibility for a disease.

Inventions 1-15 and 59-73 are related as product and process of use. Inventions 1-15 are drawn to a group of patentably distinct nucleic acid sequences selected from the group of SEQ ID NOs:1-15, and Inventions 59-73 are drawn to a method of using a nucleotide fragment selected from the group of SEQ ID NOs:1-15. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a nucleotide sequence selected from the group of SEQ ID NOs:1-15 can be used in a materially different process for using that product such as for molecularly labeling a member of a group consisting of an autoimmune disease, a pathology associated with an autoimmune disease, a pathological pregnancy or an unsuccessful pregnancy.

Inventions 29-73 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are patentably distinct methods because they comprise different modes of operation and result in distinctly different outcomes. The invention of Groups 29-43 is distinguished from the methods of Group 44-58 and 59-73

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because it includes the step of identifying and quantifying any nucleotide fragment in any biological body material and this step is not included in the methods of Group 44-58 and 59-73. The outcome of the method of Group 29-43 comprises detecting a cell expressing a nucleotide fragment which has been identified and quantified, which is distinctly different from the outcome of Group 44-58, which is the diagnosis of a autoimmune condition or a pathological pregnancy or an unsuccessful pregnancy, and is distinctly different from the outcome of Group 59-73 which is the detection of susceptibility of an autoimmune condition or a pathological pregnancy or an unsuccessful pregnancy. The invention of Group 44-58 is distinguished from the methods of Group 29-43 and 59-73 because it includes the step of using a molecular marker to diagnose a condition, while the method of Group 29-43 comprises steps to molecularly label a condition and the method of Group 44-58 comprises the step of diagnosing susceptibility of a condition by using a chromosomal marker for a condition. The outcome of the method of Group 44-58 comprises the diagnosis of an autoimmune condition or a pathological pregnancy or an unsuccessful pregnancy, which is distinctly different from the outcome of Group 29-43, which is detection of a cell expressing a nucleotide fragment which has been identified and quantified and is distinctly different from the outcome of Group 59-73 which is detection of susceptibility to an autoimmune condition or a pathological pregnancy or an unsuccessful pregnancy. The invention of Group 44-58 is distinguished from the methods of Group 29-43 and 44-58 because it includes steps to detect genes associated with susceptibility of a condition and does not actually detect the condition itself. The outcome of Group 59-73 is detection of

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susceptibility of an autoimmune condition or a pathological pregnancy or an unsuccessful pregnancy, which is distinctly different from the outcome of the method of Group 29-43, comprising detection of a cell expressing a nucleotide fragment which has been identified and quantified, and distinct from the outcome of Invention 44-58, which is the diagnosis of a autoimmune condition or a pathological pregnancy or an unsuccessful pregnancy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
9/19/2005


DAVID GUZO
PRIMARY EXAMINER